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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,091	06/04/2001	Deborah Charych	1680.002	6042

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EXAMINER	
TRAN, MY CHAU T	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/874,091	CHARYCH ET AL.	
	Examiner	Art Unit	
	MY-CHAU T. TRAN	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,60-73,79-91 and 97-101* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,60-73,79-91 and 97-98* is/are rejected.

7)☒ Claim(s) *99 and 100* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Application and Claims Status

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/07/2005 has been entered.

2. Applicant's amendment filed 04/06/2005 is acknowledged and entered. Claims 92-96 have been canceled. Claims 1, and 73 have been amended. Claims 97-101 have been added.

3. Claims 1, and 73 were amended and Claims 92-96 were added by the amendment filed on 07/30/2004.

4. Claims 55-59,and 74-78 were canceled and Claims 1, 60-61, 72-73, and 79-80 were amended by the amendment filed on 03/18/2004.

5. Claims 2-20, and 53 are canceled; Claim 1 was amended; and Claims 55-91 were added by the amendment filed on 06/30/2003.

6. Claims 21-52, and 54 are canceled, and Claims 3, 9, 16, and 20 were amended by the amendment filed on 12/09/2002.

7. Claims 1, 60-73, 79-91, and 97-101 are pending.

Priority

8. This application claims benefit to a provisional application under 35 U.S.C 119(e). The provisional application is 60/209,711 filed 06/05/2000.

9. Claims 1, 60-73, 79-91, and 97-101 are treated on the merit in this Office Action.

Withdrawn Rejection(s)

10. The rejection of claims 1, 60-72, and 92 under 35 USC 112, first paragraph (new matter) has been withdrawn in light of applicant's amendments of claim 1 wherein the limitation of "*a silicon dioxide coating configured to amplify a fluorescent signal from a labeled protein bound to the array*" is deleted.

11. The rejection of claims 73, 79-91, and 93 under 35 USC 112, first paragraph (new matter) has been withdrawn in view of applicant's amendments of claim 73 wherein the limitation of "*a silicon dioxide coating configured to amplify a fluorescent signal from a labeled protein bound to the array*" is deleted.

12. The rejection of claims 1, 60-61, 63-66, 73, 79-80, 82-85, and 92-93 under 35 USC 103(a) as being obvious over Gustafson et al. (US Patent 5,478,527) and Pease et al. (US Patent 5,831,070) has been withdrawn in view of applicant's amendments of claims 1 and 73, addition of claims 97-101, and cancellation of claims 92-93.

13. The rejection of claims 62, and 81 under 35 USC 103(a) as being obvious over Gustafson et al. (US Patent 5,478,527) and Pease et al. (US Patent 5,831,070) as applied to claims 1, 60-61, 63-64, 73, 79-80, 82-83, and 92-93, and further in view of Wagner et al. (US Patent 6,406,921 B1) has been withdrawn in view of applicant's amendments of claims 1 and 73, addition of claims 97-101, and cancellation of claims 92-93.

14. The rejection of claims 67-72, and 86-91 under 35 USC 103(a) as being obvious over Gustafson et al. (US Patent 5,478,527) and Pease et al. (US Patent 5,831,070) as applied to claims 1, 60-61, 63-64, 73, 79-80, 82-83, and 92-93, and further in view of Barrett et al (US Patent 5,482,867) has been withdrawn in view of applicant's amendments of claims 1 and 73, addition of claims 97-101, and cancellation of claims 92-93.

New Rejection(s) – Necessitated by Amendment

15. Claims 1, 60-73, 79-91, and 97-101 are treated on the merit in this Office Action.

Claim Objections

16. Claims 99-101 are objected to because of the following informalities: Claim 99 recites "*the method of claim 1*". However, claim 1 is not a method claim but a product claim. Claims 100 and 101, which depend on claim 99, also recite "*the method of*". Thus, claims 99-101 are objected. Additionally, it is interpreted that claims 99-101 refers to the array of claim 1, i.e. the product claim, since there in no pending method claims and in order to further prosecution. Appropriate correction is required.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 1, 60-61, 63-66 and 99-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gustafson et al. (US Patent 5,478,527) and Chenchik et al. (US Patent 6,087,102).

Gustafson et al. disclose a biograting comprises a wafer for attachment of binding agents that comprises zone of active and inactive binding reagent (refers to the instant claimed array/product) (see e.g. Abstract; col. 2, lines 34-67; col. 5, lines 1-10; fig. 1). The binding agents include proteins (see e.g. col. 4, lines 6-32; col. 7, lines 5-15, and 23-35). The biograting comprises a wafer that is defined as an optically flat plate of insoluble solid (see e.g. col. 4, lines 62-63; col. 5, lines 1-10; fig. 1, ref. #14), a metal layer on the wafer (see e.g. col. 5, lines 1-10, and 51-60; fig. 1, ref. #12), and a transparent layer on the metal layer (see e.g. col. 5, lines 1-10, and lines 61-63; col. 11, lines 15-28; fig. 1, ref. #2). The wafer comprises silicon or glass (see e.g. col. 5, lines 36-50; col. 8, lines 25-31; col. 11, lines 15-28). The metal layer comprises metals such as aluminum (see e.g. col. 5, lines 11-16; col. 11, lines 15-28). The transparent layer comprises materials such as silicon dioxide (see e.g. col. 5, lines 17-26; col. 11, lines 15-28). The thickness of the silicon dioxide layer is between 800 to 1200 Å (see e.g. col. 3, lines 11-12; col. 6, lines 51-55; col. 9, lines 60-65; col. 10, lines 3-6) and the silicon dioxide is treated with a reagent such as aminopropyltriethoxysilane (see e.g. col. 6, lines 16-38; col. 11, lines 15-28). The aminosilane are functionalized with functional group such as amino, and thiol group for attachment of the binding agents (see e.g. col. 7, lines 23-63). Additionally, Gustafson et al. disclose a masking technique that creates zones of active binding reagent (ref. #8 of fig. 1) and zones of inactive binding reagent that produces a diffraction grating design (ref. #10 of fig. 1) (see e.g. col. 5, lines 1-10; col. 8, lines 25-64; col. 9, lines 27-40). Gustafson et al. define the

term "diffraction grating" "*to include gratings which are formed in one or more immunological steps. For the method of this invention, the diffraction grating is formed directly by the conjugation of the non-light disturbing binding reagent on the insoluble surface with a light disturbing analyte*" (see e.g. col. 4, lines 41-58). That is the term "diffraction grating" includes immunoassay step wherein the label analyte bind with the binding pair on the surface of the support and the label produces a light signal.

The array of Gustafson et al. differs from the presently claimed invention by failing to include a plurality of fluorescent labeled proteins.

Chenchik et al. disclose an arrays of polymeric targets stably associated with the surface of a support (see e.g. Abstract; col. 2, lines 3-11, and 51-62). The polymeric targets are bipolymeric compounds that include naturally occurring polymeric compounds or mimetics or analogues of naturally occurring polymeric compounds, and the bipolymeric compounds includes peptides, polypeptides and proteins (see e.g. col. 3, lines 13-20). The support comprises a planar configuration and one or more modification layers (see e.g. col. 4, lines 25-67). The material of the support includes glass, plastic, or metal (see e.g. col. 4, lines 43-52). The modification layer includes layer such as metal oxide (see e.g. col. 4, lines 53-67). The polymeric targets are stably associated with the surface of a support via covalent or non-covalent association that includes attachment through a linking group (see e.g. col. 3, line 65 thru col. 4, line 14). Additionally, Chenchik et al. disclose the application of the array wherein the sample of probes are bound to the polymeric targets on the support by either hybridization of specific binding (see e.g. col. 8, lines 55-62). The probes include peptidic probes and label such as cyanine dyes, e.g. Cy3 and Cy5 (see e.g. col. 9, lines 18-65). Following binding the probe and

the polymeric targets, the resulting conjugation patterns of labeled probe can be visualized or detected (see col. 10, lines 38-45). Chenchik et al. also disclose packaging the array in a kit format wherein the kit includes reagents such as labels (see e.g. col. 11, lines 25-39).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a plurality of fluorescent labeled proteins as taught by Chenchik et al. in the array of Gustafson et al. One of ordinary skill in the art would have been motivated to include a plurality of fluorescent labeled proteins in the array of Gustafson et al. for the advantage of providing a high throughput format that provides two types of informations, which are the types of genes expressed and the size of the expressed products (Chenchik: col. 1, lines 38-43) since both Gustafson et al. and Chenchik et al. disclose an array of polymeric compounds such as proteins (Gustafson: col. 4, lines 6-32; Chenchik: col. 2, lines 3-11). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Gustafson et al. and Chenchik et al. because Chenchik et al. disclose by examples the success of including plurality of fluorescent labeled probe that binds to the target on the surface of the support (Chenchik: col. 11, line 61 thru col. 15, lines 22).

20. Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gustafson et al. (US Patent 5,478,527) and Chenchik et al. (US Patent 6,087,102) as applied to claims 1, 60-61, 63-66 and 99-101 above, and further in view of Wagner et al. (US Patent 6,329,209 B1).

Gustafson et al. disclose a biograting comprises a wafer for attachment of binding agents that comprises zone of active and inactive binding reagent (refers to the instant claimed array/product) (see e.g. Abstract; col. 2, lines 34-67; col. 5, lines 1-10; fig. 1). The binding

agents include proteins (see e.g. col. 4, lines 6-32; col. 7, lines 5-15, and 23-35). The biograting comprises a wafer that is defined as an optically flat plate of insoluble solid (see e.g. col. 4, lines 62-63; col. 5, lines 1-10; fig. 1, ref. #14), a metal layer on the wafer (see e.g. col. 5, lines 1-10, and 51-60; fig. 1, ref. #12), and a transparent layer on the metal layer (see e.g. col. 5, lines 1-10, and lines 61-63; col. 11, lines 15-28; fig. 1, ref. #2). The wafer comprises silicon or glass (see e.g. col. 5, lines 36-50; col. 8, lines 25-31; col. 11, lines 15-28). The metal layer comprises metals such as aluminum (see e.g. col. 5, lines 11-16; col. 11, lines 15-28). The transparent layer comprises materials such as silicon dioxide (see e.g. col. 5, lines 17-26; col. 11, lines 15-28). The thickness of the silicon dioxide layer is between 800 to 1200 Å (see e.g. col. 3, lines 11-12; col. 6, lines 51-55; col. 9, lines 60-65; col. 10, lines 3-6) and the silicon dioxide is treated with a reagent such as aminopropyltriethoxysilane (see e.g. col. 6, lines 16-38; col. 11, lines 15-28). The aminosilane are functionalized with functional group such as amino, and thiol group for attachment of the binding agents (see e.g. col. 7, lines 23-63). Additionally, Gustafson et al. disclose a masking technique that creates zones of active binding reagent (ref. #8 of fig. 1) and zones of inactive binding reagent that produces a diffraction grating design (ref. #10 of fig. 1) (see e.g. col. 5, lines 1-10; col. 8, lines 25-64; col. 9, lines 27-40). Gustafson et al. define the term "diffraction grating" "*to include gratings which are formed in one or more immunological steps. For the method of this invention, the diffraction grating is formed directly by the conjugation of the non-light disturbing binding reagent on the insoluble surface with a light disturbing analyte*" (see e.g. col. 4, lines 41-58). That is the term "diffraction grating" includes immunoassay step wherein the label analyte bind with the binding pair on the surface of the support and the label produces a light signal.

Chenchik et al. disclose an arrays of polymeric targets stably associated with the surface of a support (see e.g. Abstract; col. 2, lines 3-11, and 51-62). The polymeric targets are bipolymeric compounds that include naturally occurring polymeric compounds or mimetics or analogues of naturally occurring polymeric compounds, and the bipolymeric compounds includes peptides, polypeptides and proteins (see e.g. col. 3, lines 13-20). The support comprises a planar configuration and one or more modification layers (see e.g. col. 4, lines 25-67). The material of the support includes glass, plastic, or metal (see e.g. col. 4, lines 43-52). The modification layer includes layer such as metal oxide (see e.g. col. 4, lines 53-67). The polymeric targets are stably associated with the surface of a support via covalent or non-covalent association that includes attachment through a linking group (see e.g. col. 3, line 65 thru col. 4, line 14). Additionally, Chenchik et al. disclose the application of the array wherein the sample of probes are bound to the polymeric targets on the support by either hybridization of specific binding (see e.g. col. 8, lines 55-62). The probes include peptidic probes and label such as cyanine dyes, e.g. Cy3 and Cy5 (see e.g. col. 9, lines 18-65). Following binding the probe and the polymeric targets, the resulting conjugation patterns of labeled probe can be visualized or detected (see col. 10, lines 38-45). Chenchik et al. also disclose packaging the array in a kit format wherein the kit includes reagents such as labels (see e.g. col. 11, lines 25-39).

Thus it is obvious to combine the array of Gustafson et al. and Chenchik et al. to produce the presently claimed array. Because one of ordinary skill in the art would have been motivated to include a plurality of fluorescent labeled proteins in the array of Gustafson et al. for the advantage of providing a high throughput format that provides two types of informations, which are the types of genes expressed and the size of the expressed products (Chenchik: col. 1, lines

38-43). However, the array combination of Gustafson et al. and Chenchik et al. differs from the presently claimed invention by failing to include a maleleimide functional group for binding with the protein binding agents.

Wagner et al. disclose an array of proteins comprising a plurality of patches in discrete, known regions on a substrate, where a protein with different, known sequence is immobilized on each patch (see e.g. Abstract; col. 3, lines 26-29; col. 4, lines 53-54; col. 6, line 61 to col. 7, line 2; col. 7, lines 16-17; col. 9, lines 58-65). The plurality of patches comprises different proteins (see e.g. col. 3, lines 26-29; col. 10, line 60 to col. 11, line 27). Additionally, Wagner et al. define the term protein to include protein analogue, wherein "*The term protein may also apply to amino acid polymers in which one or more amino acid residues is an artificial chemical analogue of a corresponding naturally occurring amino acid*" (see e.g. col. 5, lines 26-29). The array comprises of a monolayer on the surface of the substrate and the proteins are immobilized on the monolayer (see e.g. col. 8, lines 9-17; col. 15, lines 33-64). They are three major classes of monolayer formation are preferably used to expose high densities of bioreactive functionalities on the array, which are alkylsiloxane monolayer, alkyl-thiol/dialkyldisulfide monolayer, and alkyl monolayer (see e.g. col. 8, lines 18-41; col. 17, lines 52 to col. 19, line 50). The functional group on the monolayer for binding with the protein includes maleleimide and N-hydroxysuccinimide (see e.g. col. 11, lines 39-53; col. 19, line 36-50). Wagner et al. also disclose that the substrate comprise organic thin film such as polyethylene glycol (chemical blocking agent/protein blocking agent) to reduce the non-specific binding of molecules to the surface (see e.g. col. 8, lines 12-15, and 35-38). Wagner et al. further disclose a system comprising an array and binding assay reagents (see e.g. col. 32, lines 49-57).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a maleleimide functional group for binding with the protein binding agents as taught by Wagner et al. in the array combination of Gustafson et al. and Chenchik et al. One of ordinary skill in the art would have been motivated to include a maleleimide functional group for binding with the protein binding agents in the array combination of Gustafson et al. and Chenchik et al. for the advantage of providing the ability to assay in parallel a multitude of proteins, and to increase the stringency of the bound capture agent by preventing non-specific binding of protein to the surface of the support (Wagner: col. 2, lines 51-54; and col. 8, lines 19-23) since Gustafson et al., Chenchik et al., and Wagner et al. all disclose an array of polymeric compounds such as proteins (Gustafson: col. 4, lines 6-32; Chenchik: col. 2, lines 3-11; Wagner: col. 3, lines 26-29). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Gustafson et al., Chenchik et al., and Wagner et al. because Wagner et al. disclose by examples the immobilization of a plurality of different proteins on a solid substrate (see e.g. col. 40, lines 31 to col. 43, line 20).

21. Claims 67-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gustafson et al. (US Patent 5,478,527) and Chenchik et al. (US Patent 6,087,102) as applied to claims 1, 60-61, 63-66 and 99-101 above, and further in view of Barrett et al (US Patent 5,482,867).

Gustafson et al. disclose a biograting comprises a wafer for attachment of binding agents that comprises zone of active and inactive binding reagent (refers to the instant claimed array/product) (see e.g. Abstract; col. 2, lines 34-67; col. 5, lines 1-10; fig. 1). The binding

agents include proteins (see e.g. col. 4, lines 6-32; col. 7, lines 5-15, and 23-35). The biograting comprises a wafer that is defined as an optically flat plate of insoluble solid (see e.g. col. 4, lines 62-63; col. 5, lines 1-10; fig. 1, ref. #14), a metal layer on the wafer (see e.g. col. 5, lines 1-10, and 51-60; fig. 1, ref. #12), and a transparent layer on the metal layer (see e.g. col. 5, lines 1-10, and lines 61-63; col. 11, lines 15-28; fig. 1, ref. #2). The wafer comprises silicon or glass (see e.g. col. 5, lines 36-50; col. 8, lines 25-31; col. 11, lines 15-28). The metal layer comprises metals such as aluminum (see e.g. col. 5, lines 11-16; col. 11, lines 15-28). The transparent layer comprises materials such as silicon dioxide (see e.g. col. 5, lines 17-26; col. 11, lines 15-28). The thickness of the silicon dioxide layer is between 800 to 1200 Å (see e.g. col. 3, lines 11-12; col. 6, lines 51-55; col. 9, lines 60-65; col. 10, lines 3-6) and the silicon dioxide is treated with a reagent such as aminopropyltriethoxysilane (see e.g. col. 6, lines 16-38; col. 11, lines 15-28). The aminosilane are functionalized with functional group such as amino, and thiol group for attachment of the binding agents (see e.g. col. 7, lines 23-63). Additionally, Gustafson et al. disclose a masking technique that creates zones of active binding reagent (ref. #8 of fig. 1) and zones of inactive binding reagent that produces a diffraction grating design (ref. #10 of fig. 1) (see e.g. col. 5, lines 1-10; col. 8, lines 25-64; col. 9, lines 27-40). Gustafson et al. define the term "diffraction grating" "*to include gratings which are formed in one or more immunological steps. For the method of this invention, the diffraction grating is formed directly by the conjugation of the non-light disturbing binding reagent on the insoluble surface with a light disturbing analyte*" (see e.g. col. 4, lines 41-58). That is the term "diffraction grating" includes immunoassay step wherein the label analyte bind with the binding pair on the surface of the support and the label produces a light signal.

Chenchik et al. disclose an arrays of polymeric targets stably associated with the surface of a support (see e.g. Abstract; col. 2, lines 3-11, and 51-62). The polymeric targets are bipolymeric compounds that include naturally occurring polymeric compounds or mimetics or analogues of naturally occurring polymeric compounds, and the bipolymeric compounds includes peptides, polypeptides and proteins (see e.g. col. 3, lines 13-20). The support comprises a planar configuration and one or more modification layers (see e.g. col. 4, lines 25-67). The material of the support includes glass, plastic, or metal (see e.g. col. 4, lines 43-52). The modification layer includes layer such as metal oxide (see e.g. col. 4, lines 53-67). The polymeric targets are stably associated with the surface of a support via covalent or non-covalent association that includes attachment through a linking group (see e.g. col. 3, line 65 thru col. 4, line 14). Additionally, Chenchik et al. disclose the application of the array wherein the sample of probes are bound to the polymeric targets on the support by either hybridization of specific binding (see e.g. col. 8, lines 55-62). The probes include peptidic probes and label such as cyanine dyes, e.g. Cy3 and Cy5 (see e.g. col. 9, lines 18-65). Following binding the probe and the polymeric targets, the resulting conjugation patterns of labeled probe can be visualized or detected (see col. 10, lines 38-45). Chenchik et al. also disclose packaging the array in a kit format wherein the kit includes reagents such as labels (see e.g. col. 11, lines 25-39).

Thus it is obvious to combine the array of Gustafson et al. and Chenchik et al. to produce the presently claimed array. Because one of ordinary skill in the art would have been motivated to include a plurality of fluorescent labeled proteins in the array of Gustafson et al. for the advantage of providing a high throughput format that provides two types of informations, which are the types of genes expressed and the size of the expressed products (Chenchik: col. 1, lines

38-43). However, the array combination of Gustafson et al. and Chenchik et al. differs from the presently claimed invention by failing to include biotin and avidin as the anchoring segment.

Barrett et al. teaches an array of immobilized ligands on predefined regions of a surface of a solid support (col. 2, lines 36-41). The method involves attaching to the surface a caged binding member (anchor). The ligand includes peptides (col. 4, lines 34-60). The caged binding member is a biotin analog (col. 5, lines 45-56). Avidin can be immobilized onto the surface of the solid support and bind to biotin (col. 5, lines 57-65). One type of biotin analog is a biotin with N-succinimidyl and a linking group of 6-aminocaproic (NHS-lc-lc-biotin) (col. 14, lines 66-67 to col. 15, lines 1-30).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the anchoring segment includes biotin and avidin as taught by Barrett et al. in the array combination of Gustafson et al. and Chenchik et al. One of ordinary skill in the art would have been motivated to include the anchoring segment includes biotin and avidin in the array combination of Gustafson et al. and Chenchik et al. for the advantage of providing an efficiently and stably attaching a broad range ligands on predefined regions of a solid support (Barrett: col. 2, lines 26-32) since Gustafson et al., Chenchik et al., and Barrett et al. all disclose an array of polymeric compounds such as proteins (Gustafson: col. 4, lines 6-32; Chenchik: col. 2, lines 3-11; Barrett: col. 2, lines 36-41). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Gustafson et al., Chenchik et al., and Barrett et al. because Barrett et al. disclose by examples the success of attaching biotin onto the support (Barrett: col. 28, line 5 thru col. 32, line 13).

22. Claims 73, 79-80, 82-85, 97, and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gustafson et al. (US Patent 5,478,527) and Chenchik et al. (US Patent 6,087,102).

Gustafson et al. disclose a biograting comprises a wafer for attachment of binding agents that comprises zone of active and inactive binding reagent (refers to the instant claimed array/product) (see e.g. Abstract; col. 2, lines 34-67; col. 5, lines 1-10; fig. 1). The binding agents include proteins (see e.g. col. 4, lines 6-32; col. 7, lines 5-15, and 23-35). The biograting comprises a wafer that is defined as an optically flat plate of insoluble solid (see e.g. col. 4, lines 62-63; col. 5, lines 1-10; fig. 1, ref. #14), a metal layer on the wafer (see e.g. col. 5, lines 1-10, and 51-60; fig. 1, ref. #12), and a transparent layer on the metal layer (see e.g. col. 5, lines 1-10, and lines 61-63; col. 11, lines 15-28; fig. 1, ref. #2). The wafer comprises silicon or glass (see e.g. col. 5, lines 36-50; col. 8, lines 25-31; col. 11, lines 15-28). The metal layer comprises metals such as aluminum (see e.g. col. 5, lines 11-16; col. 11, lines 15-28). The transparent layer comprises materials such as silicon dioxide (see e.g. col. 5, lines 17-26; col. 11, lines 15-28). The thickness of the silicon dioxide layer is between 800 to 1200 Å (see e.g. col. 3, lines 11-12; col. 6, lines 51-55; col. 9, lines 60-65; col. 10, lines 3-6) and the silicon dioxide is treated with a reagent such as aminopropyltriethoxysilane (see e.g. col. 6, lines 16-38; col. 11, lines 15-28). The aminosilane are functionalized with functional group such as amino, and thiol group for attachment of the binding agents (see e.g. col. 7, lines 23-63). Additionally, Gustafson et al. disclose a masking technique that creates zones of active binding reagent (ref. #8 of fig. 1) and zones of inactive binding reagent that produces a diffraction grating design (ref. #10 of fig. 1) (see e.g. col. 5, lines 1-10; col. 8, lines 25-64; col. 9, lines 27-40). Gustafson et al. define the

term "diffraction grating" "*to include gratings which are formed in one or more immunological steps. For the method of this invention, the diffraction grating is formed directly by the conjugation of the non-light disturbing binding reagent on the insoluble surface with a light disturbing analyte*" (see e.g. col. 4, lines 41-58). That is the term "diffraction grating" includes immunoassay step wherein the label analyte bind with the binding pair on the surface of the support and the label produces a light signal.

The array of Gustafson et al. differs from the presently claimed invention by failing to include packaging the array into a kit format that include a label reagent.

Chenchik et al. disclose an arrays of polymeric targets stably associated with the surface of a support (see e.g. Abstract; col. 2, lines 3-11, and 51-62). The polymeric targets are bipolymeric compounds that include naturally occurring polymeric compounds or mimetics or analogues of naturally occurring polymeric compounds, and the bipolymeric compounds includes peptides, polypeptides and proteins (see e.g. col. 3, lines 13-20). The support comprises a planar configuration and one or more modification layers (see e.g. col. 4, lines 25-67). The material of the support includes glass, plastic, or metal (see e.g. col. 4, lines 43-52). The modification layer includes layer such as metal oxide (see e.g. col. 4, lines 53-67). The polymeric targets are stably associated with the surface of a support via covalent or non-covalent association that includes attachment through a linking group (see e.g. col. 3, line 65 thru col. 4, line 14). Additionally, Chenchik et al. disclose the application of the array wherein the sample of probes are bound to the polymeric targets on the support by either hybridization of specific binding (see e.g. col. 8, lines 55-62). The probes include peptidic probes and label such as cyanine dyes, e.g. Cy3 and Cy5 (see e.g. col. 9, lines 18-65). Following binding the probe and

the polymeric targets, the resulting conjugation patterns of labeled probe can be visualized or detected (see col. 10, lines 38-45). Chenchik et al. also disclose packaging the array in a kit format wherein the kit includes reagents such as labels (see e.g. col. 11, lines 25-39).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include packaging the array into a kit format that include a label reagent as taught by Chenchik et al. in the array of Gustafson et al. One of ordinary skill in the art would have been motivated to include packaging the array into a kit format that include a label reagent in the array of Gustafson et al. for the advantage of providing a high throughput format that provides two types of informations, which are the types of genes expressed and the size of the expressed products (Chenchik: col. 1, lines 38-43) since both Gustafson et al. and Chenchik et al. disclose an array of polymeric compounds such as proteins (Gustafson: col. 4, lines 6-32; Chenchik: col. 2, lines 3-11). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Gustafson et al. and Chenchik et al. because Chenchik et al. disclose by examples the success of including plurality of fluorescent labeled probe that binds to the target on the surface of the support (Chenchik: col. 11, line 61 thru col. 15, lines 22).

23. Claim 81 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gustafson et al. (US Patent 5,478,527) and Chenchik et al. (US Patent 6,087,102) as applied to claims 73, 79-80, 82-85, 97, and 98 above, and further in view of Wagner et al. (US Patent 6,329,209 B1).

Gustafson et al. disclose a biograting comprises a wafer for attachment of binding agents that comprises zone of active and inactive binding reagent (refers to the instant claimed

array/product) (see e.g. Abstract; col. 2, lines 34-67; col. 5, lines 1-10; fig. 1). The binding agents include proteins (see e.g. col. 4, lines 6-32; col. 7, lines 5-15, and 23-35). The biograting comprises a wafer that is defined as an optically flat plate of insoluble solid (see e.g. col. 4, lines 62-63; col. 5, lines 1-10; fig. 1, ref. #14), a metal layer on the wafer (see e.g. col. 5, lines 1-10, and 51-60; fig. 1, ref. #12), and a transparent layer on the metal layer (see e.g. col. 5, lines 1-10, and lines 61-63; col. 11, lines 15-28; fig. 1, ref. #2). The wafer comprises silicon or glass (see e.g. col. 5, lines 36-50; col. 8, lines 25-31; col. 11, lines 15-28). The metal layer comprises metals such as aluminum (see e.g. col. 5, lines 11-16; col. 11, lines 15-28). The transparent layer comprises materials such as silicon dioxide (see e.g. col. 5, lines 17-26; col. 11, lines 15-28). The thickness of the silicon dioxide layer is between 800 to 1200 Å (see e.g. col. 3, lines 11-12; col. 6, lines 51-55; col. 9, lines 60-65; col. 10, lines 3-6) and the silicon dioxide is treated with a reagent such as aminopropyltriethoxysilane (see e.g. col. 6, lines 16-38; col. 11, lines 15-28). The aminosilane are functionalized with functional group such as amino, and thiol group for attachment of the binding agents (see e.g. col. 7, lines 23-63). Additionally, Gustafson et al. disclose a masking technique that creates zones of active binding reagent (ref. #8 of fig. 1) and zones of inactive binding reagent that produces a diffraction grating design (ref. #10 of fig. 1) (see e.g. col. 5, lines 1-10; col. 8, lines 25-64; col. 9, lines 27-40). Gustafson et al. define the term "diffraction grating" "*to include gratings which are formed in one or more immunological steps. For the method of this invention, the diffraction grating is formed directly by the conjugation of the non-light disturbing binding reagent on the insoluble surface with a light disturbing analyte*" (see e.g. col. 4, lines 41-58). That is the term "diffraction grating" includes

immunoassay step wherein the label analyte bind with the binding pair on the surface of the support and the label produces a light signal.

Chenchik et al. disclose an arrays of polymeric targets stably associated with the surface of a support (see e.g. Abstract; col. 2, lines 3-11, and 51-62). The polymeric targets are bipolymeric compounds that include naturally occurring polymeric compounds or mimetics or analogues of naturally occurring polymeric compounds, and the bipolymeric compounds includes peptides, polypeptides and proteins (see e.g. col. 3, lines 13-20). The support comprises a planar configuration and one or more modification layers (see e.g. col. 4, lines 25-67). The material of the support includes glass, plastic, or metal (see e.g. col. 4, lines 43-52). The modification layer includes layer such as metal oxide (see e.g. col. 4, lines 53-67). The polymeric targets are stably associated with the surface of a support via covalent or non-covalent association that includes attachment through a linking group (see e.g. col. 3, line 65 thru col. 4, line 14). Additionally, Chenchik et al. disclose the application of the array wherein the sample of probes are bound to the polymeric targets on the support by either hybridization of specific binding (see e.g. col. 8, lines 55-62). The probes include peptidic probes and label such as cyanine dyes, e.g. Cy3 and Cy5 (see e.g. col. 9, lines 18-65). Following binding the probe and the polymeric targets, the resulting conjugation patterns of labeled probe can be visualized or detected (see col. 10, lines 38-45). Chenchik et al. also disclose packaging the array in a kit format wherein the kit includes reagents such as labels (see e.g. col. 11, lines 25-39).

Thus it is obvious to combine the array of Gustafson et al. and Chenchik et al. to produce the presently claimed array. Because one of ordinary skill in the art would have been motivated to include a plurality of fluorescent labeled proteins in the array of Gustafson et al. for the

advantage of providing a high throughput format that provides two types of informations, which are the types of genes expressed and the size of the expressed products (Chenchik: col. 1, lines 38-43). However, the array combination of Gustafson et al. and Chenchik et al. differs from the presently claimed invention by failing to include a maleleimide functional group for binding with the protein binding agents.

Wagner et al. disclose an array of proteins comprising a plurality of patches in discrete, known regions on a substrate, where a protein with different, known sequence is immobilized on each patch (see e.g. Abstract; col. 3, lines 26-29; col. 4, lines 53-54; col. 6, line 61 to col. 7, line 2; col. 7, lines 16-17; col. 9, lines 58-65). The plurality of patches comprises different proteins (see e.g. col. 3, lines 26-29; col. 10, line 60 to col. 11, line 27). Additionally, Wagner et al. define the term protein to include protein analogue, wherein "*The term protein may also apply to amino acid polymers in which one or more amino acid residues is an artificial chemical analogue of a corresponding naturally occurring amino acid*" (see e.g. col. 5, lines 26-29). The array comprises of a monolayer on the surface of the substrate and the proteins are immobilized on the monolayer (see e.g. col. 8, lines 9-17; col. 15, lines 33-64). They are three major classes of monolayer formation are preferably used to expose high densities of bioreactive functionalities on the array, which are alkylsiloxane monolayer, alkyl-thiol/dialkyldisulfide monolayer, and alkyl monolayer (see e.g. col. 8, lines 18-41; col. 17, lines 52 to col. 19, line 50). The functional group on the monolayer for binding with the protein includes maleleimide and N-hydroxysuccinimide (see e.g. col. 11, lines 39-53; col. 19, line 36-50). Wagner et al. also disclose that the substrate comprise organic thin film such as polyethylene glycol (chemical blocking agent/protein blocking agent) to reduce the non-specific binding of molecules to the

surface (see e.g. col. 8, lines 12-15, and 35-38). Wagner et al. further disclose a system comprising an array and binding assay reagents (see e.g. col. 32, lines 49-57).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a maleleimide functional group for binding with the protein binding agents as taught by Wagner et al. in the array combination of Gustafson et al. and Chenchik et al. One of ordinary skill in the art would have been motivated to include a maleleimide functional group for binding with the protein binding agents in the array combination of Gustafson et al. and Chenchik et al. for the advantage of providing the ability to assay in parallel a multitude of proteins, and to increase the stringency of the bound capture agent by preventing non-specific binding of protein to the surface of the support (Wagner: col. 2, lines 51-54; and col. 8, lines 19-23) since Gustafson et al., Chenchik et al., and Wagner et al. all disclose an array of polymeric compounds such as proteins (Gustafson: col. 4, lines 6-32; Chenchik: col. 2, lines 3-11; Wagner: col. 3, lines 26-29). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Gustafson et al., Chenchik et al., and Wagner et al. because Wagner et al. disclose by examples the immobilization of a plurality of different proteins on a solid substrate (see e.g. col. 40, lines 31 to col. 43, line 20).

24. Claims 86-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gustafson et al. (US Patent 5,478,527) and Chenchik et al. (US Patent 6,087,102) as applied to claims 73, 79-80, 82-85, 97, and 98 above, and further in view of Barrett et al (US Patent 5,482,867).

Gustafson et al. disclose a biograting comprises a wafer for attachment of binding agents that comprises zone of active and inactive binding reagent (refers to the instant claimed array/product) (see e.g. Abstract; col. 2, lines 34-67; col. 5, lines 1-10; fig. 1). The binding agents include proteins (see e.g. col. 4, lines 6-32; col. 7, lines 5-15, and 23-35). The biograting comprises a wafer that is defined as an optically flat plate of insoluble solid (see e.g. col. 4, lines 62-63; col. 5, lines 1-10; fig. 1, ref. #14), a metal layer on the wafer (see e.g. col. 5, lines 1-10, and 51-60; fig. 1, ref. #12), and a transparent layer on the metal layer (see e.g. col. 5, lines 1-10, and lines 61-63; col. 11, lines 15-28; fig. 1, ref. #2). The wafer comprises silicon or glass (see e.g. col. 5, lines 36-50; col. 8, lines 25-31; col. 11, lines 15-28). The metal layer comprises metals such as aluminum (see e.g. col. 5, lines 11-16; col. 11, lines 15-28). The transparent layer comprises materials such as silicon dioxide (see e.g. col. 5, lines 17-26; col. 11, lines 15-28). The thickness of the silicon dioxide layer is between 800 to 1200 Å (see e.g. col. 3, lines 11-12; col. 6, lines 51-55; col. 9, lines 60-65; col. 10, lines 3-6) and the silicon dioxide is treated with a reagent such as aminopropyltriethoxysilane (see e.g. col. 6, lines 16-38; col. 11, lines 15-28). The aminosilane are functionalized with functional group such as amino, and thiol group for attachment of the binding agents (see e.g. col. 7, lines 23-63). Additionally, Gustafson et al. disclose a masking technique that creates zones of active binding reagent (ref. #8 of fig. 1) and zones of inactive binding reagent that produces a diffraction grating design (ref. #10 of fig. 1) (see e.g. col. 5, lines 1-10; col. 8, lines 25-64; col. 9, lines 27-40). Gustafson et al. define the term "diffraction grating" "*to include gratings which are formed in one or more immunological steps. For the method of this invention, the diffraction grating is formed directly by the conjugation of the non-light disturbing binding reagent on the insoluble surface with a light*

disturbing analyte" (see e.g. col. 4, lines 41-58). That is the term "diffraction grating" includes immunoassay step wherein the label analyte bind with the binding pair on the surface of the support and the label produces a light signal.

Chenchik et al. disclose an arrays of polymeric targets stably associated with the surface of a support (see e.g. Abstract; col. 2, lines 3-11, and 51-62). The polymeric targets are bipolymeric compounds that include naturally occurring polymeric compounds or mimetics or analogues of naturally occurring polymeric compounds, and the bipolymeric compounds includes peptides, polypeptides and proteins (see e.g. col. 3, lines 13-20). The support comprises a planar configuration and one or more modification layers (see e.g. col. 4, lines 25-67). The material of the support includes glass, plastic, or metal (see e.g. col. 4, lines 43-52). The modification layer includes layer such as metal oxide (see e.g. col. 4, lines 53-67). The polymeric targets are stably associated with the surface of a support via covalent or non-covalent association that includes attachment through a linking group (see e.g. col. 3, line 65 thru col. 4, line 14). Additionally, Chenchik et al. disclose the application of the array wherein the sample of probes are bound to the polymeric targets on the support by either hybridization of specific binding (see e.g. col. 8, lines 55-62). The probes include peptidic probes and label such as cyanine dyes, e.g. Cy3 and Cy5 (see e.g. col. 9, lines 18-65). Following binding the probe and the polymeric targets, the resulting conjugation patterns of labeled probe can be visualized or detected (see col. 10, lines 38-45). Chenchik et al. also disclose packaging the array in a kit format wherein the kit includes reagents such as labels (see e.g. col. 11, lines 25-39).

Thus it is obvious to combine the array of Gustafson et al. and Chenchik et al. to produce the presently claimed array. Because one of ordinary skill in the art would have been motivated

to include a plurality of fluorescent labeled proteins in the array of Gustafson et al. for the advantage of providing a high throughput format that provides two types of informations, which are the types of genes expressed and the size of the expressed products (Chenchik: col. 1, lines 38-43). However, the array combination of Gustafson et al. and Chenchik et al. differs from the presently claimed invention by failing to include biotin and avidin as the anchoring segment.

Barrett et al. teaches an array of immobilized ligands on predefined regions of a surface of a solid support (col. 2, lines 36-41). The method involves attaching to the surface a caged binding member (anchor). The ligand includes peptides (col. 4, lines 34-60). The caged binding member is a biotin analog (col. 5, lines 45-56). Avidin can be immobilized onto the surface of the solid support and bind to biotin (col. 5, lines 57-65). One type of biotin analog is a biotin with N-succinimidyl and a linking group of 6-aminocaproic (NHS-lc-lc-biotin) (col. 14, lines 66-67 to col. 15, lines 1-30).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the anchoring segment includes biotin and avidin as taught by Barrett et al. in the array combination of Gustafson et al. and Chenchik et al. One of ordinary skill in the art would have been motivated to include the anchoring segment includes biotin and avidin in the array combination of Gustafson et al. and Chenchik et al. for the advantage of providing an efficiently and stably attaching a broad range ligands on predefined regions of a solid support (Barrett: col. 2, lines 26-32) since Gustafson et al., Chenchik et al., and Barrett et al. all disclose an array of polymeric compounds such as proteins (Gustafson: col. 4, lines 6-32; Chenchik: col. 2, lines 3-11; Barrett: col. 2, lines 36-41). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Gustafson et al.,

Chenchik et al., and Barrett et al. because Barrett et al. disclose by examples the success of attaching biotin onto the support (Barrett: col. 28, line 5 thru col. 32, line 13).

Response to Amendment

25. The declaration under 37 CFR 1.132 filed 04/06/2005 is insufficient to overcome the rejections of claims 1, 60-73, 79-91, and 97-101 based upon the cited prior art of Gustafson et al. (US Patent 5,478,527) because:

a. The expert opinion by Dr. Deborah Charych in the declaration under 37 CFR 1.132 is inadequate to overcome the rejections of 1, 60-73, 79-91, and 97-101 based upon the cited prior art of Gustafson et al. (US Patent 5,478,527) because there is no factual evidence supporting the statement. That is the expert opinion by Dr. Deborah Charych fails to set forth facts that Gustafson et al. lacks disclosure of the specific critical range of the silicon dioxide, which is 200-900 Å, as claimed in the instant array such as a data showing the testing of both inside and outside the claimed range to show the criticality of the claimed range as indicated in the Advisory Action mailed 02/08/2005. (See MPEP § 716.01(c)). Below is the reiteration of the Advisory Action with regard to the issue of the specific critical range of the silicon dioxide, which is 200-900 Å:

"Applicant's argument that Gustafson et al. lacks disclosure of the specific critical range of the silicon dioxide cited in claim 92 and 93, which is 200-900 Å, is not convincing because applicant's allegation regarding the criticality of range thickness of silicon dioxide in claim 92 and 93 do not rise to the level of factual evidence. Although applicant has indicated that support for this allegation is found in the present application

disclosure, specifically pg. 21, lines 13-18, this disclosure does not provide factual support for applicant's allegation regarding the criticality of range thickness of silicon dioxide. Objective evidence, which ***must be factually supported*** *by an appropriate affidavit or declaration, to be of probative value includes evidence of unexpected results... See, for example, In re De Blauwe, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984) ("It is well settled that unexpected results must be established by factual evidence"). Lastly, any differences between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected. In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (In MPEP § 716.02). Additionally, to establish unexpected results over a claimed range,* ***applicants should compare a sufficient number of tests both inside and outside the claimed range to show the criticality of the claimed range****. In re Hill, 284 F.2d 955, 128 USPQ 197 (CCPA 1960) (In MPEP § 716.02(d) (II)).*"

b. The expert opinion by Dr. Deborah Charych in the declaration under 37 CFR 1.132 is inadequate to overcome the rejections of 1, 60-73, 79-91, and 97-101 based upon the cited prior art of Gustafson et al. (US Patent 5,478,527) because there is no factual evidence supporting the statement. That is the expert opinion by Dr. Deborah Charych fails to set forth facts that the substrate of Gustafson is designed for labeled free assay only such as a side-by-side comparison of the prior art array and the presently claimed array. (See MPEP § 716.01(c))

26. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness. Therefore, the declaration under 37 CFR 1.132 is insufficient to overcome the rejections of claims1, 60-73, 79-91, and 97-101 based upon the cited prior art of Gustafson et al. (US Patent 5,478,527).

Response to Arguments

27. Applicant's arguments filed 04/06/2005 have been fully considered but they are not persuasive. Applicant's argument is for the rejections of claims 1, 60-73, 79-91, and 97-101 based upon the cited prior art of Gustafson et al. (US Patent 5,478,527).

First, applicant contends that the array of Gustafson et al. lacks disclosure of the specific critical range of the silicon dioxide, which is 200-900 Å, as claimed in the instant array. Applicant supports this assertion by providing an expert opinion by Dr. Deborah Charych in the declaration under 37 CFR 1.132. However, the expert opinion by Dr. Deborah Charych in the declaration under 37 CFR 1.132 is inadequate to overcome this rejection because there is no factual evidence supporting the statement, i.e. there is no data showing the testing of both inside and outside the claimed range to show the criticality of the claimed range (see MPEP § 716.02(d) (II)) and the discussion in paragraph 25 above).

Second, applicant argue that the array of Gustafson et al. is designed for labeled free assay only and supports this assertion by providing an expert opinion by Dr. Deborah Charych in the declaration under 37 CFR 1.132. Applicant's arguments are not convincing that the array of Gustafson et al. is designed for labeled free assay only because Gustafson et al. define the term "diffraction grating" "*to include gratings which are formed in one or more immunological steps.*

For the method of this invention, the diffraction grating is formed directly by the conjugation of the non-light disturbing binding reagent on the insoluble surface with a light disturbing analyte" (see e.g. col. 4, lines 41-58). That is the term "diffraction grating" includes immunoassay step wherein the label analyte bind with the binding pair on the surface of the support and the label produces a light signal. Thus, the array of Gustafson et al. does not exclude labeled assay. Additionally, the expert opinion by Dr. Deborah Charych in the declaration under 37 CFR 1.132 is inadequate to overcome this rejection because there is no factual evidence supporting the statement (see discussion in paragraph 25 above).

Thus, the array of Gustafson et al. is obvious over the presently claimed array and the rejections based upon the cited prior art of Gustafson et al. (US Patent 5,478,527) are maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
April 27, 2005

PADMASHRI PONNALURI
PRIMARY EXAMINER